

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	<p style="text-align: center;">Master File No. 2:12-MD-02327 MDL 2327</p> <p style="text-align: center;">JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</p>
THIS DOCUMENT RELATES TO: WAVE 1 CASES	

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF JUAN C. FELIX, M.D.**

Dr. Juan C. Felix is a gynecologic pathologist with decades of experience in the field. The cases to which this Response applies are identified in Ex. A. In this litigation, Dr. Felix offers opinions regarding characteristics of the TVT mesh and clinical-pathological correlations of the mesh, as well as criticisms of the opinions offered by Plaintiffs' expert pathologist—Dr. Vladimir Iakovlev. *See generally* Ex. B, Expert Report of Juan C. Felix, M.D. ("Felix Report").¹

In their Motion, Plaintiffs first seek to exclude the entirety of Dr. Felix's opinions by making a conclusory challenge to his qualifications despite his vast experience in the field of gynecologic pathology. Plaintiffs then challenge Dr. Felix's methodology, complaining that they have not had the opportunity to examine records or documentation relating to the explants Dr. Felix examined over the course of his decades of clinical experience, an argument this Court has rejected before. They also erroneously claim that Dr. Felix has not done a proper literature review.

¹ Dr. Felix submitted three expert reports in connection with Wave 1, each dealing with a specific product or set of products: (i) TVT, TVT-O, TVT-Exact, and TVT-Abbrevio; (ii) Ethicon mesh products for pelvic organ prolapse repair; and (iii) TVT-Secur. To prevent confusion, all references to the "Felix Report" in this Response pertain to Dr. Felix's Report addressing TVT, TVT-O, TVT-Exact, and TVT-Abbrevio.

Plaintiffs also challenge the reliability of Dr. Felix's specific opinions about degradation, contracture, pain, cytotoxicity, and particle loss. Plaintiffs' misunderstand, overstate, and oversimplify Dr. Felix's opinions, which are based on his knowledge, experience, education, training and review of relevant medical literature. The Court should reject Plaintiffs' challenge on that basis.

ARGUMENT

I. Dr. Felix Will Not Testify About Degradation Due To The Presence Of Xylene Or About Oxygenation.

Ethicon does not intend to offer Dr. Felix to testify about whether the Prolene used in Ethicon mesh products degrades. As discussed in Section III.D, however, Dr. Felix will opine about the methodology Dr. Iakovlev used in claiming that he can detect degradation. In addition, Ethicon will not elicit testimony from Dr. Felix regarding xylene degradation of Ethicon mesh products or oxygenation. The Court should, therefore, deny Plaintiffs' Motion on these issues as moot.

II. Dr. Felix Is Well-qualified To Offer His Opinions.

Plaintiffs do not challenge Dr. Felix's qualifications as an anatomic pathologist and cytopathologist. Motion at 4. Rather, they simply argue that Dr. Felix "exceeds the bounds of his qualifications." *Id.* Yet, nowhere in Plaintiffs' brief do they actually identify any opinions that exceed the scope of Dr. Felix's qualifications. The Court should reject Plaintiffs' conclusory argument.

Dr. Felix is eminently qualified to offer his opinions as an expert pathologist in this case. He is a board-certified anatomic pathologist, with added qualification in cytopathology. *See* Ex. B, Felix Report at 2. Significantly, unlike Dr. Iakovlev, whose qualifications are limited to general anatomic pathology, Dr. Felix also has specialized training in gynecological pathology.

See id. Indeed, in striking contrast with Dr. Iakovlev, Dr. Felix's pre-litigation experience includes the histological analysis of numerous vaginal meshes sent to him in the context of his normal gynecologic pathology practice.

Dr. Felix completed a fellowship in obstetrical and gynecological pathology and has practiced in this field for decades. *See id.* He has had numerous academic appointments including Assistant Professor of Pathology at Cornell University and Assistant Professor, Associate Professor, and, presently, full Professor of Clinical Pathology and Obstetrics & Gynecology at Keck School of Medicine at the University of Southern California. Ex. C, Felix Report at Ex. A, Felix CV, 2–3. He has also had a number of clinical appointments in pathology, anatomic pathology, cytopathology, and surgical pathology. *Id.*

Dr. Felix is currently Chief of Cytopathology and Chief of Obstetrical and Gynecological Pathology at the Los Angeles County-University of Southern California Women's Hospital, one of the largest women's hospitals in the United States. *Id.*; Ex. B, Felix Report at 2. He has published more than 110 peer-reviewed articles and authored eight textbook chapters. *Id.* at 2–3. He has also given lectures on gynecological pathology around the world, and served as an expert reviewer for numerous leading scientific and medical journals in the field. *Id.*

Dr. Felix is well-qualified to testify in the field of pathology, and Plaintiffs offer no challenge on this point. As explained below, each of Dr. Felix's specific opinions relate to and are based on his knowledge, experience, education, and training, as well as his review of pertinent medical literature. For these reasons, the Court should deny Plaintiffs' Motion.

III. Dr. Felix's Opinions Are Based On Reliable Methodology.

A. Dr. Felix's opinions are properly based on his knowledge, skill, experience, training, and education in pathology.

Over the course of more than 22 years practicing in gynecologic pathology at the University of Southern California, Dr. Felix has looked at more than 50 mesh specimens. *Id.* at 3, 20. In this litigation, Dr. Felix relies, in part, on this knowledge of the “typical” (*i.e.*, non-symptomatic) pathological presentation of a mesh implant to conclude that Dr. Iakovlev's mesh slides were also typical. *Id.* at 9.²

Plaintiffs challenge Dr. Felix's opinions on the grounds that he “has not bothered to disclose the protocol or criteria for the collection, evaluation, or testing of these specimens.” Motion at 7. They also claim that without documentation or medical records, “Dr. Felix's recollections cannot be confirmed or tested, [and] they cannot be effectively rebutted[.]” *Id.*

Plaintiffs' arguments are without merit. As this Court has explained, “If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.” Mem. Op. and Order (*Daubert* Motions) at 40, *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014) [Doc. #265]. Like Dr. Robboy in *Bellew*, Dr. Felix does not intend to offer specific opinions about the meshes he has reviewed during his more than 22 years of experience. Rather, like Dr.

² Plaintiffs do not even accurately describe that experience. For example, Plaintiffs claim that Dr. Felix admits that most of the mesh samples he examined are from around the year 2000. Motion at 7. Plaintiffs misstate Dr. Felix's testimony. Dr. Felix testified that his department received more pelvic mesh explants during that time-period, as opposed to an even two or three a year for 22 years, because the use of slings to treat stress urinary incontinence was a relatively new development at that time. Pls.' Motion Ex. C, Felix 10/5/15 Dep. Tr. 50:25-51:10. Curiously, Plaintiffs also claim that Dr. Felix has not “reviewed a single slide or record relating to those explants.” Motion at 7. Plaintiffs' assertion makes no sense, because Dr. Felix testified that he reviewed them in the course of his practice. Pls.' Motion Ex. C, Felix 10/5/15 Dep. Tr. 50:25-51:10.

Robboy, Dr. Felix has compared a set of mesh slides to what he views as “typical” in his clinical experience.

Federal Rule of Evidence 702 provides that an expert may offer an opinion to assist the trier of fact if the expert is qualified by “knowledge, skill, experience, training, or education.” In addition, pursuant to Federal Rule of Evidence 703:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If an expert in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

As the Supreme Court of the United States explained in the seminal case of *Kumho Tire Co. v. Carmichael*:

Experts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called “general truths derived from . . . specialized experience.” And whether the specific expert testimony focuses upon specialized observations, the specialized translation of those observations into theory, a specialized theory itself, or the application of such a theory in a particular case, the expert’s testimony will often rest “upon an experience confessedly foreign in kind to [the jury’s] own.”

526 U.S. 137, 148–49 (1999) (citations omitted).

Dr. Felix’s opinions are based not only on his decades of “knowledge, skill, experience, training, [and] education” as a gynecologic pathologist, but his experience analyzing surgical mesh explants during the course of his general practice. Plaintiffs’ claims that they cannot verify Dr. Felix’s findings—which were made in the context of his practice treating patients, rather than in connection with a publication or litigation—are immaterial because he is not seeking to offer specific opinions regarding meshes that are not at issue in this litigation. For this reason, the Court should deny Plaintiffs’ Motion.

B. Plaintiffs’ arguments regarding Dr. Felix’s review of the scientific literature do not withstand scrutiny.

Plaintiffs’ Motion asserts that Dr. Felix “cites to almost no scientific literature, studies, or other support for his disagreements with Dr. Iakovlev[,]” but Plaintiffs are tilting at windmills. Motion at 8. Indeed, Dr. Felix’s Report—including the section of the Report directed specifically at Dr. Iakovlev’s opinions—is replete with citations to scientific authority, and his reliance list contains hundreds of publications. *See* Ex. B, Felix Report at 11–30 (addressing Dr. Iakovlev’s opinions). Plaintiffs do not challenge Dr. Felix’s reliance on a single one of those authorities, but instead simply ignore their existence.

Plaintiffs also claim that Dr. Felix “did not perform a comprehensive literature review[,]” and bases his opinions “upon the documents and literature that defense counsel selected for him.” Motion at 8. But the testimony Plaintiffs cite in support of this assertion highlights the bankruptcy of their argument. Specifically, Plaintiffs point to an excerpt in which *Plaintiffs’ counsel*—not Dr. Felix—states that Dr. Felix’s “reliance list was created by counsel for Ethicon and is incomplete or inaccurate.” *Id.* (citing Pls.’ Motion Ex. D, Felix 3/28/2016 *Ruiz* Dep. Tr. 19:7-11). And while Dr. Felix based his opinions, in part, on internal Ethicon documents provided by Ethicon’s counsel, *id.* (citing Pls.’ Motion Ex. E, Felix 3/28/2016 *Loustaunau* Dep. Tr. 61:13–62:15), Plaintiffs ignore the fact that Dr. Felix requested those materials from Ethicon’s counsel because he would have no other way to acquire internal Ethicon documents. In short, Plaintiffs failed to cite support for their claim that Dr. Felix failed to conduct a proper review of scientific and medical literature.³

³ Plaintiffs’ allegation that the literature cited by Dr. Felix is “cherry-picked,” Motion at 8, rings hollow because, while Plaintiffs do not identify any literature that Dr. Felix neglected, Dr. Felix explains throughout his Report why the literature written and relied on by Dr. Iakovlev does not support his opinions. *See, e.g.*, Ex. B, Felix Report at 12, 17, 19, 24-26.

Finally, Dr. Felix’s opinions are not based solely on a literature review, but rather are also based on his knowledge, experience, training, and education. *Cf. Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473–74 (M.D.N.C. 2006) (cited by Plaintiffs at footnote 8 on page 8 of their Motion) (holding “[w]here proffered expert testimony is not based on independent research, but instead on such a literature review,” review must be reliable).

As a result, Plaintiffs’ arguments regarding Dr. Felix’s reliance on scientific and medical literature are baseless, and should be rejected by this Court.

C. Dr. Felix properly used slides prepared by Dr. Iakovlev in formulating his opinions.

Plaintiffs challenge Dr. Felix’s review of the pathological evidence in this litigation, arguing that Dr. Felix’s opinions are unreliable because he did not prepare the slides himself. Motion at 8. Specifically, Plaintiffs assert that “both Plaintiff and defense experts were provided with equal amounts of pathology from the Plaintiffs’ cases[,]” but Dr. Felix’s “opinions are based entirely upon the slides prepared, and the work performed, by Dr. Iakovlev.” Motion at 8. Plaintiffs’ argument is meritless.

As an initial matter, Plaintiffs failed to identify any support for their contention that a pathologist cannot form opinions based on slides created by another pathologist.

More importantly, Plaintiffs’ argument ignores the fact that Plaintiffs—not Ethicon—bear the burden of establishing that the pathology at issue contains features supporting their claims. In this litigation, Dr. Felix reviewed Dr. Iakovlev’s slides, and found that his opinions lack any basis in the field of pathology. *See* Ex. B, Felix Report at 17-22, 26-36. If Dr. Felix had reviewed a different set of slides and found no evidence of the features that Dr. Iakovlev claims to have observed, Plaintiffs would certainly argue that Dr. Felix’s opinions are unreliable and

irrelevant because he examined different slides. Put simply, Plaintiffs cannot take both sides of the coin.

Similarly, Plaintiffs' argument is predicated on the flawed assumption that it would not assist the jury for the pathologists for both parties to review the same pathology material. Plaintiffs appear to forget—on this point and throughout their Motion—that Dr. Felix's "examin[ation] and critici[sm] of the work of" Dr. Iakovlev "is one of the traditional roles of an expert." *See Fuji Elec. Corp. of Am. v. Fireman's Fund Ins.*, No. 9:05CV27, 2005 WL 5960354, at *2 (E.D. Tex. Nov. 21, 2005).

Plaintiffs' argument because it has no basis in law or science, and the Court should deny Plaintiffs' Motion on this issue.

D. Dr. Felix's degradation opinions are limited to the methodology utilized by Dr. Iakovlev as a pathologist and are reliable.

Plaintiffs seek to exclude Dr. Felix's opinions regarding the alleged degradation of the Prolene used in Ethicon mesh products. *See* Motion at 8–11. Specifically, Plaintiffs assert that Dr. Felix seeks to opine that Prolene does not degrade *in vivo*, but that his opinion is unreliable because he purportedly failed to support his opinion with scientific literature. *See id.* Plaintiffs' arguments, however, amount to nothing but a straw man.

Ethicon will not elicit testimony from Dr. Felix on the question of whether or not Prolene degrades. Rather, as discussed in his Report, Dr. Felix will testify as a pathologist about the numerous methodological flaws inherent in Dr. Iakovlev's degradation opinions. Ex. B, Felix Report at 24–30.

Specifically, Dr. Felix will explain that the methodology employed by Dr. Iakovlev is not generally accepted in the field of pathology as a means of determining whether a polymer, such as the Prolene used in Ethicon mesh products, degrades *in vivo*. *See id.* Similarly, Dr. Felix will

testify that not only are Dr. Iakovlev's degradation theories unsupported by pathological medical literature, but even Dr. Iakovlev's own publications cast doubt on his opinions. *See id.* at 25–27. Dr. Felix will also opine as to his findings regarding the histological slides he has examined. *See id.* at 28–38. In addition, Dr. Felix will testify that there is no support—in the medical literature or in the histological slides he has reviewed—for the notion that any alleged degradation has any clinical significance. *See id.* at 29–32.

Dr. Felix will also base his opinions regarding Dr. Iakovlev's degradation opinions on testing conducted by Dr. Steven MacLean, an expert for Ethicon in this litigation. Ex. B, Felix Report at 28; Ex. D, Expert Report of Dr. Steven MacLean ("MacLean Report"). As explained in Dr. MacLean's expert report, he intentionally oxidized Prolene mesh samples, and then applied the same histological stains used by Dr. Iakovlev to the samples to determine whether the Prolene retained the stain. *See id.* at 54–68. Specifically, Dr. MacLean intentionally oxidized Prolene mesh samples using two different approaches: (i) exposure to ultraviolet radiation, and (ii) exposure to the oxidative medium used by Drs. Scott Guelcher and Russell Dunn, experts for plaintiffs in pelvic mesh litigation. *Id.* at 54–56. Dr. MacLean's analysis of the meshes using both approaches proved that even intentionally oxidized Prolene does not trap histological stain. *Id.* at 57–61. Dr. Felix will testify that this reliable scientific testing confirms his opinions that Dr. Iakovlev's methodology is unsound. Ex. B, Felix Report at 28.

Although Plaintiffs' argue that Dr. Felix should be precluded from relying on Dr. MacLean's work, they do not include any specific arguments as to why Dr. MacLean's testing is unreliable, and instead incorporate by reference a motion to exclude Dr. MacLean's opinions filed in the *Mullins* litigation, as well as their motion to exclude Dr. MacLean's opinions to be filed in this litigation. Motion at 11. Ethicon relies on and incorporates by reference its Response

in Opposition to Plaintiffs’ Motion to Exclude the Opinions and Testimony of Dr. MacLean in *Mullins, et al. v. Ethicon, Inc., et al.* No. 2:12-cv-02952 (S.D. W. Va. Nov. 9, 2015) [Doc. #227], and its response in opposition to Plaintiffs’ forthcoming motion to exclude Dr. MacLean’s opinions in this litigation.

Dr. Felix’s opinions regarding degradation pertain solely to questions of pathology. Dr. Felix’s education, training, and experience, as well as his review of relevant scientific literature, demonstrate the reliability of his opinions. Accordingly, the Court should deny Plaintiffs’ Motion as it relates to Dr. Felix’s degradation opinions.

E. Dr. Felix’s contracture opinions are reliable.

Plaintiffs claim that Dr. Felix’s opinion regarding mesh contracture amounts to the following: “I have not seen it, so it does not happen.” Motion at 6; *see also id.* at 11–13. This is an inaccurate and oversimplified representation of Dr. Felix’s opinions.

Dr. Felix does not seek to opine that Ethicon’s mesh products cannot contract. Rather, Dr. Felix will opine that Dr. Iakovlev’s opinions that such contracture occurs *in vivo* is not based on a sound methodology.

In his Report, Dr. Felix criticizes Dr. Iakovlev’s claim that “scar tissue contracts during maturation, which leads to contraction of the mesh-scar composite structure and results in overtightening that compresses tissues and organs[.]” Ex. B, Felix Report at 16. As Dr. Felix explains, this opinion “lacks reliable scientific evidence of *in vivo* contraction and is clinically unfounded based on compilation of clinical studies in meta-analyses.” *Id.* Dr. Felix opines that if mesh contracted as Dr. Iakovlev claims, then there would be many instances of urethral occlusion causing urinary obstruction based on where the mesh is located and the structure of the urethra. *Id.* at 16–17. Dr. Felix will testify that he has not observed these complications in his

analysis of mesh explants in his practice or in this litigation, and that two large-scale reviews support his opinions. *Id.* at 16.

Dr. Felix also opines that Dr. Iakovlev failed to account for “artifacts of excision and fixation” well-known in the field of pathology, including the elasticity of the tissue from which the specimens are excised and the use of formalin in the sample preparation process. *Id.* at 24 (explaining that “formalin fixation will cause excised tissue to further contract due to the cross-linking of proteins and collagen”).

In addition, Plaintiffs’ argument that Dr. Felix’s opinions regarding contracture should be excluded because he cannot explain why mesh might contract in the abdomen is misguided. Motion at 12. It is not Dr. Felix’s duty to explain why mesh might contract in another application. “One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.” *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). To the extent Plaintiffs believe the failure to explain why mesh could contract in the abdomen is even relevant to the opinion that it does not contract in the transvaginal space, then that is a matter for cross-examination, not exclusion.

F. Plaintiffs’ arguments regarding Dr. Felix’s pain opinions are without basis.

Plaintiffs claim in their motion that “Dr. Felix cannot opine that the TVT does not cause pain.” Motion at 13. But Plaintiffs’ argument is an erroneous representation of Dr. Felix’s opinions.⁴

Dr. Felix does not opine, as Plaintiffs claim, that “TVT does not cause pain.” Rather, Dr. Felix will explain to the jury that Dr. Iakovlev’s opinions regarding pain are inconsistent with the methodology followed by pathologists. Specifically, Dr. Felix will explain that the medicine and

⁴ By its own terms, Plaintiffs’ Motion limits their argument regarding Dr. Felix’s pain opinions to TVT. Motion at 13. Plaintiffs, therefore, appear to concede that Dr. Felix may offer opinions regarding pain in all cases not pertaining to TVT.

science of pathology do not permit a pathologist to conclude that a patient experienced pain based on what the pathologist observes in a slide. *See, e.g.*, Ex. B, Felix Report at 9 (“In the case of equating histological findings found in mesh explants to the sensation of pain, there is no body of evidence supporting that any given finding unequivocally predicts pain”). Dr. Felix will testify that Dr. Iakovlev’s assertions to the contrary have no basis in the field of pathology. *See, e.g.*, Ex. E, S. Lester, *Manual of Surgical Pathology*, at 3 (2010) (“It has been shown that pathologists cannot accurately predict clinical information from the glass slides alone.”).

Applying the appropriate scientific methods, Dr. Felix based his opinions on, among other things, his review of Dr. Iakovlev’s photomicrographs and slides, as well as his own experience examining meshes over the past 22 years. Dr. Iakovlev’s meshes, Dr. Felix explains, had the same histological presentation as the typical meshes Dr. Felix has analyzed in his clinical practice. *See* Ex. B, Felix Report at 20. Dr. Felix will testify that, because Dr. Iakovlev made no such comparison, his opinion that the patients whose mesh he examined suffered from pain is speculative. *Id.* at 22 (explaining that the Hill study, which found no correlation between pain and inflammation or fibrosis, does not support Dr. Iakovlev’s attempts to correlate pain with his histological observations).

Dr. Felix will also explain that Dr. Iakovlev’s opinions regarding pain based on his pathological slides is inconsistent with fundamental principles of pathology and medical facts. *See id.* at 21 (explaining that Dr. Iakovlev’s findings regarding the degree of innervation in the vagina are “incorrect and not supported by the scientific and medical literature”); *id.* at 21-22 (opining that Dr. Iakovlev “has no basis to assert that the nerves seen in his specimens are abnormal,” and that his methods and theories are “not generally accepted in the fields of gynecologic pathology or surgical pathology”); *id.* at 22 (explaining that Dr. Iakovlev failed to

identify the sensory nerve receptors necessary to determine whether a nerve can detect and transmit pain signals); *id.* at 23 (explaining that Dr. Iakovlev fails to recognize that thromboses, capillary occlusions, and small arterioles are “commonplace throughout the body and have never been shown to be associated with pain”).

Thus, Dr. Felix’s opinions regarding Dr. Iakovlev’s failure to follow a proper methodology are not merely “unsupported assertions that Dr. Iakovlev is wrong.” Motion at 14. Instead, Dr. Felix’s opinions are reliable scientific findings based on his knowledge, education, training, and experience as a pathologist, as well as his review of pathology and relevant medical literature.⁵ Dr. Felix will thus “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *See Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1993). Accordingly, the Court should deny Plaintiffs’ Motion.

G. Dr. Felix’s opinions about cytotoxicity and particle loss are admissible.

Plaintiffs argue that Dr. Felix should be precluded from offering opinions regarding the alleged cytotoxicity of TVT because his opinion is based on his own pathological experience and the fact that Dr. Iakovlev has not reported any evidence of cytotoxicity. Motion at 14-15. Plaintiffs assert that Dr. Iakovlev’s observations have “no bearing on whether the mesh in TVT is cytotoxic,” and Dr. Felix’s experience is “not sufficient” for him to “render a reliable opinion on the subject.” *Id.* at 15. Once again, Plaintiffs oversimplify and misunderstand Dr. Felix’s opinions.

Dr. Felix will opine that he has never seen any evidence that TVT is cytotoxic *in vivo*. *See* Ex. B, Felix Report at 41. Dr. Felix bases this opinion on his review of the pathology in this litigation, Dr. Iakovlev’s photomicrographs, as well as his 20 years of experience analyzing mesh

⁵ Notably, Plaintiffs do not challenge Dr. Felix’s examination of the slides or his findings.

explants. *See id.* Thus, Dr. Felix does not merely opine that TVT is not cytotoxic because “has never personally noticed cytotoxicity in his own practice,” as Plaintiffs suggest. Rather, Dr. Felix opines that—based on his education, training, and experience, as well as his review of relevant medical literature, Dr. Iakovlev’s photomicrographs, and the pathology in his clinical practice and this litigation—he has not seen any evidence that TVT is cytotoxic *in vivo*. Dr. Felix’s opinion on this issue is reliable and helpful to the jury, and should be permitted on this basis. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 727 (S.D. W. Va. 2014) (permitting Dr. Pramudji’s opinion that she has not seen degradation in her clinical practice).

In addition, Plaintiffs fail to grasp the significance of the fact that Dr. Iakovlev has made no findings that TVT is cytotoxic. Plaintiffs have not disclosed a toxicologist in this litigation, and have not presented any reliable scientific or medical evidence proving that TVT is cytotoxic *in vivo*. The fact that their own pathologist has not reported any evidence of cytotoxicity in the slides he has examined shows that they cannot do so. It is entirely appropriate for Dr. Felix to note that Dr. Iakovlev does not report any evidence of cytotoxicity, and Plaintiffs do not challenge his qualifications or methodology in doing so.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Juan C. Felix, M.D.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
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IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 1 CASES	

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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